SLOVENSKI STANDARD
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Vsadki (implantati) za srce in ožilje - Proteze za srčno zaklopko - 3. del: Nadomestki srčne zaklopke, vsajeni (implantirani) s transkatetrsko metodo (ISO/DIS 5840-3:2019)

Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques (ISO/DIS 5840-3:2019)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 3: Durch minimal-invasive Methoden implantierter Herzklappenersatz (ISO/DIS 5840-3:2019)

Implants cardiovasculaires - Prothèses valvulaires - Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter (ISO/DIS 5840-3:2019)

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11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

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Cardiovascular implants — Cardiac valve prostheses —

Part 3: Heart valve substitutes implanted by transcatheter techniques

Implants cardiovasculaires — Prothèses valvulaires —

Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems.*

This second edition of ISO 5840-3 cancels and replaces the first edition (ISO 5840-3:2013), which has been technically revised.

ISO 5840 consists of the following parts, under the general title *Cardiovascular implants — Cardiac valve prostheses:*

— *Part 1: General requirements*

— *Part 2: Surgically implanted heart valve substitutes*

— *Part 3: Heart valve substitutes implanted by transcatheter techniques*

Introduction

This part of ISO 5840 has been prepared for transcatheter heart valve substitutes with emphasis on providing guidance for *in vitro* testing, preclinical *in vivo* and clinical evaluations, reporting of all *in vitro*, preclinical *in vivo*, and clinical evaluations and labelling and packaging of the device. This process is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent issues.

This part of ISO 5840 is to be used in conjunction with ISO 5840 parts 1 and 2.

Cardiovascular implants — Cardiac valve prostheses —

Part 3:
Heart valve substitutes implanted by transcatheter techniques

1 Scope

This part of ISO 5840 is applicable to all devices intended for implantation as a transcatheter heart valve substitute (see Annex A for examples).

This part of ISO 5840 is applicable to both newly developed and modified transcatheter heart valve substitutes and to the accessory devices, packaging and labelling required for their implantation and for determining the appropriate size of heart valve substitute to be implanted.

This part of ISO 5840 outlines an approach for verifying/validating the design and manufacture of a transcatheter heart valve substitute through risk management. The selection of appropriate verification/validation tests and methods are to be derived from the risk assessment. The tests may include those to assess the physical, chemical, biological and mechanical properties of heart valve substitutes and of their materials and components. The tests can also include those for preclinical *in vivo* evaluation and clinical evaluation of the finished heart valve substitute.

This part of ISO 5840 defines operational conditions and performance requirements for transcatheter heart valve substitutes where adequate scientific and/or clinical evidence exists for their justification.

This part of ISO 5840 includes considerations for implantation of a transcatheter heart valve substitute inside a pre-existing prosthetic device (e.g. valve-in-valve and valve-in-ring configurations).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM F2079-09 Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents

ISO 5840-1, Cardiovascular implants – Cardiac valve prostheses – Part 1: General requirements

ISO 5840-2, Cardiovascular implants – Cardiac valve prostheses – Part 2: Surgically implanted heart valve substitutes

ISO 10555-1, Sterile, single-use intravascular catheters — Part 1: General requirements

ISO 10993-2, Biological evaluation of medical devices — Part 2: Animal welfare requirements

ISO 14155, Clinical investigation of medical devices for human subjects — Good clinical practice

ISO 14630, Non-active surgical implants — General requirements

ISO 14971, Medical devices — Application of risk management to medical devices

ISO 25539-1, Cardiovascular implants — Endovascular devices — Part 1: Endovascular prostheses

IEC 60601, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

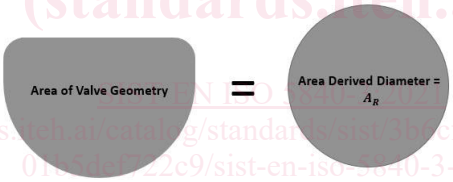
IEC 62366, Medical devices — Application of usability engineering to medical devices

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 5840-1 and the following apply.

3.1
area-derived valve diameter
A_R
calculated valve diameter based on area of the implanted device (e.g. a “D-Shaped” transcatheter mitral valve implantation (TMVI) device; see Figure 1)

NOTE 1 to entry: This approach is typically used for sizing TMVI devices where valves are designed for a non-circular geometry.



$$\text{Area Derived Diameter} = \sqrt{4A_R/\pi}$$

Figure 1 — Area-derived valve diameter for a non-circular device

3.2
delivery approach
anatomical access used to deliver the implant to the implant site (e.g. transfemoral, transapical, transseptal)

3.3
delivery system
catheter or other system used to deliver the implant to the implant site

3.4
implant loading

process to affix or attach a transcatheter heart valve substitute onto a delivery device and collapse the valve (e.g. reduce its diameter) for insertion via the delivery system (e.g. catheter), performed either during manufacture or in the clinic

3.5
neo-LVOT
region between native anterior mitral leaflet/TMVI and septal wall, proximal to the aortic valve (see Figure 2)

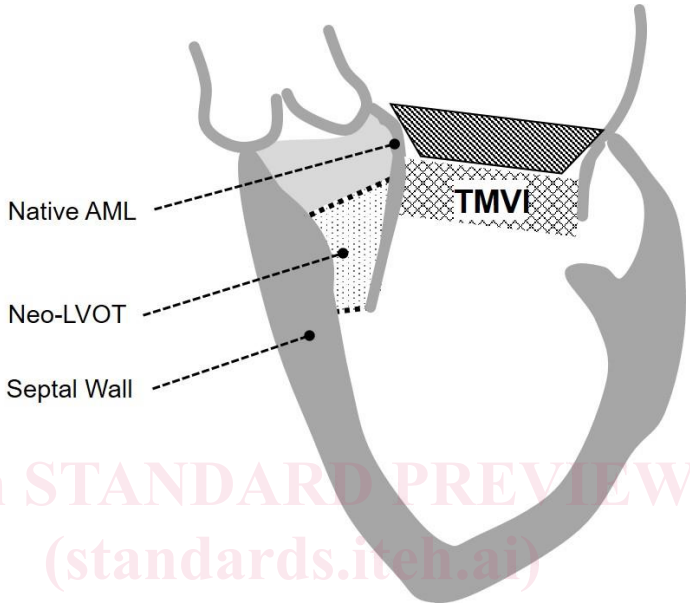


Figure 2 — Neo-LVOT formation behind a mitral leaflet

3.6
neo-sinus
region between implanted transcatheter aortic valve leaflet and native aortic leaflet/leaflet of existing bioprosthetic valve (see Figure 3)

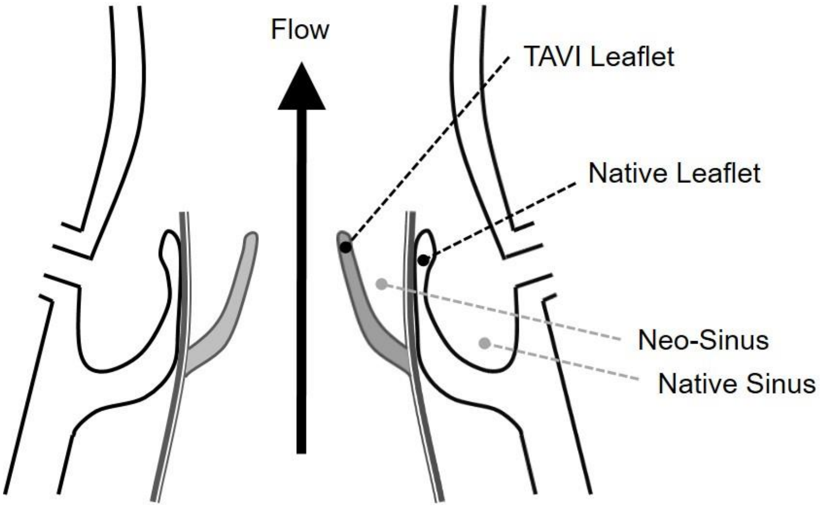


Figure 3 — Neo-sinus formation behind an aortic leaflet

3.7
perimeter derived valve diameter
calculated valve diameter (mm) based on perimeter of the implanted device

Note to entry: this approach is typically used for sizing transcatheter aortic valve implantation (TAVI) devices where valves are designed in circular geometries.

3.8
repositioning
change in implant position of a partially or fully deployed transcatheter heart valve substitute via a transcatheter technique, possibly requiring full or partial recapturing of the device

3.9
retrieval
removal of a partially or fully deployed transcatheter heart valve substitute via a transcatheter technique

3.10
transcatheter heart valve system
implantable transcatheter device, delivery system, accessories, packaging, labels and instructions for use

3.11
valve-in-ring
implantation of a transcatheter heart valve substitute into a pre-existing annuloplasty ring

3.12
valve-in-valve
implantation of a transcatheter heart valve substitute into a pre-existing heart valve substitute

4 Abbreviations

For the purposes of this part of ISO 5840, the following abbreviations apply.

AE	Adverse Event
AWT	Accelerated Wear Testing
CIP	Clinical Investigation Plan
CT	Computed Tomography
ECG	Electrocardiogram
EOA	Effective Orifice Area
IFU	Instructions For Use
LA	Left Atrium
LAA	Left Atrial Appendage
LV	Left Ventricle, Left Ventricular
LVOT	Left Ventricular Outflow Tract
MRI	Magnetic Resonance Imaging
MR	Mitral Regurgitation
PVL	Paravalvular Leakage
SAE	Serious Adverse Event
TAVI	Transcatheter Aortic Valve Implantation [also known as Transcatheter Aortic Valve Replacement (TAVR)]
TEE	Transoesophageal Echo
TMVI	Transcatheter Mitral Valve Implantation [also known as Transcatheter Mitral Valve Replacement (TMVR)]
TTE	Transthoracic Echo
ViV	Valve-in-Valve

ViR	Valve-in-Ring

5 Fundamental requirements

Refer to ISO 5840-1.

6 Device description

6.1 General

Refer to ISO 5840-1.

6.2 Intended use

Refer to ISO 5840-1.

6.3 Design inputs

6.3.1 Operational specifications

Refer to ISO 5840-1.

6.3.2 Performance specifications

6.3.2.1 General

Refer to ISO 5840-1 for general requirements. Specific transcatheter system requirements are listed in 6.3.2.2-6.3.2.4.

6.3.2.2 Transcatheter heart valve system

The design attributes to meet the intended performance of the transcatheter heart valve system shall take into account at least the following:

a) the visibility of the transcatheter heart valve system under fluoroscopy or other imaging modalities;

b) the deliverability and implantability in the target population.

6.3.2.3 Implantable device

The intended performance of the transcatheter heart valve substitute shall include, but not be limited to the following:

a) the ability to be consistently, accurately and safely loaded onto the delivery system;

b) the ability to be consistently, accurately and safely deployed;

c) the ability to be safely retrieved and/or repositioned (if applicable);

d) the ability to ensure effective fixation or anchoring within the implant site;

e) the ability to maintain structural and functional integrity;

f) the ability to conform or interact with anatomical structures within the implant site (e.g. in the aortic position, there is potential for interaction with coronary ostia, anterior mitral leaflet, AV node; in the mitral position, there is potential for interaction with the aortic root, LA, LAA, LVOT and the subvalvular apparatus);

g) the ability to conform or interact with previously implanted device (e.g. surgical valve, annuloplasty ring, transcatheter valve, valve docking device), if applicable;

h) the ability to allow forward flow with acceptably small mean pressure difference in all anticipated configurations;

i) the ability to prevent retrograde flow with acceptably small regurgitation, including paravalvular leakage;

j) the ability to resist migration and embolization;

k) avoid haemolysis;

l) the ability to resist thrombus formation;

m) biocompatible;

n) maintains its functionality and sterility for a reasonable shelf life prior to implantation;

o) has reproducible function.

6.3.2.4 Delivery system

The design attributes to meet the intended performance of the delivery system shall include, but not be limited to the following:

a) the ability to permit consistent, accurate and safe access, delivery, placement and deployment of the transcatheter heart valve substitute to the intended implant site;

b) the ability to permit consistent and safe withdrawal;

c) the ability to resist haemolysis;

d) the ability to resist thrombus formation;

e) the ability to resist blood loss (haemostasis);

f) the ability to recapture, retrieve, reposition and/or remove the transcatheter heart valve substitute (if applicable);

g) the ability to resist particulate generation.